

Application No. 09/836,627
Filing Date: April 17, 2001
Docket No. 6514-11-BHJ

Applicants submit that there is support for claim 31 in the specification on page 3, line 19-30. In particular, lines 21-25 provide support for capsules having a sealing on the gap between capsule body and cap. Applicants submit that page 3, lines 1-2 and 8-10 provides support that empty capsules may be precoated as suggested in claims 21 and 25.

The specification must be complete enough to enable one of ordinary skill in the art to make and use the invention without undue experimentation. The specification need not describe the conventional nor disclose what the skilled already possess.

White Consolidated Industries, Inc. v. Vega Servo-Control, Inc., 214 USPQ 796, 823 (Mich. 1982). Applicants submit that filling two halves of a capsule with a caplet, as in claim 24, is known to those skilled in the art as taught by the Paolos reference.

Applicants have canceled claims 26 and 27, without prejudice.

In the Office Action, claim 10 stands rejected under 35 U.S.C. §112, second paragraph as being indefinite. Applicants traverse this rejection. Applicants have amended claim 10 to remove the tradename.

Accordingly, Applicants respectfully submit that all of the rejections under 35 U.S.C. §112 have been overcome and withdrawal of these rejections is appropriate.

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Rejections under 35 U.S.C. §102

Claims 1-10, 14-16, 19-20 and 28-30 have been rejected under 35 U.S.C. §102(b) as being anticipated by EP 754,452 issued to Hatano et al. Applicants traverse these rejections.

By way of review, the present invention is directed to a drug delivery system which includes the use of a HPMC capsule which may contain a drug and have a single aqueous coating such that a drug will be released from the capsule either in the small intestine or the colon. More particularly, Applicants have surprisingly found that a single aqueous coating will enable the drug to be released from the capsule in the desired area.

Applicants submit that no new matter has been added by the amendment to claim 1 and support of such an amendment can be found in Applicants' specification on page 4, line 9-page 5, line 17.

In the Office Action, Hatano is cited for its disclosure of a drug delivery composition comprising a HPMC capsule provided with a coating for delivering a drug in the small intestine or colon. Applicants submit that the drug delivery composition in Hatano requires multiple coatings: (1) a polymer film soluble at low pH and (2) an enteric coating film. (Hatano p. 3, lines 7-10; p. 9, lines 3-7.) Additionally, Hatano

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discloses that non-aqueous based coatings are used to coat a capsule. (see p. 13, lines 30-p. 16, line 27)

Claim 18 is rejected under 35 U.S.C. §102(e) as being anticipated by Tanida et al (EP 919228B1). The Office Action cites Tanida for its disclosure of a HPMC capsule to which a coating is applied in the range of 5-20 mg/cm² of capsule surface for releasing a drug in the colon and/or terminal ileum. Applicants submit that Tanida discloses that the capsule has a double-coated structure where the surface is required to be coated with a cationic copolymer and an anionic copolymer. (Tanida, p. 3 lines 20-21).

Anticipation under 35 U.S.C. §102 requires the presence of a single art disclosure of all elements of a claimed invention arranged as in the claim. *Connell v. Sears Roebuck & Co.*, 722 F.2d 1542, 220 U.S.P.Q. (Fed. Cir. 1983). Applicants submit that neither Hatano nor Tanida disclose Applicants' invention where a HPMC capsule is provided with a single aqueous coating. Therefore, Applicants respectfully submit that neither Hatano nor Tanida disclose each and every element of the Applicants' invention. Accordingly, Applicants submit that withdrawal of these rejections is appropriate.

Rejections under 35 U.S.C. §103

Claims 1-24 and 28-31 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hatano et al as applied to claims 1-10, 14-16, 19-20 and 28-30 and

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further in view of Watts, Tanida et al and Paulos. The rejection of these claims is respectfully traversed on the grounds that the Examiner has failed to demonstrate a *prima facie* case of obviousness.

As discussed above, Applicants submit that Hatano discloses that multiple coatings must be used with its drug delivery composition. In particular, the drug delivery composition in Hatano requires multiple coatings: (1) a polymer film soluble at low pH and (2) an enteric coating film. (Hatano p. 3, lines 7-10; p. 9, lines 3-7.) Additionally, Hatano discloses that non-aqueous based coatings are used to coat a capsule. (see p. 13, lines 30-p. 16, line 27). It is a well settled principle that to establish a *prima facie* case of obviousness of a claimed invention under 35 U.S.C. §103, all the claim limitations must be taught or suggested by the prior art. MPEP 2143.03, *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Accordingly, Applicants submit that the Applicants' invention having a single aqueous coating is not obvious in view of Hatano.

The Office Action alleges that Watts discloses the use of a redox sensitive material in the coating of the HPMC capsule. Hatano teaches that a multiple coatings must be used. Applicants submit that the combined teachings of Hatano and Watts when taken for their entirety do not teach or suggest the Applicants' invention. Applicants note that Watts discloses the use of non-aqueous coatings and does mention that an aqueous coating is possible (Watts p. 9, line 23-24), however, Applicants submit that this is a mere invitation to experiment and does not teach or

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suggest Applicants' invention. Applicants submit that there is no teaching or suggestion in the combined teachings of Watts and Hatano to arrive at the Applicants' claimed invention with its surprising results.

The Office Action alleges that Paolos teaches that filling a capsule with a caplet. The Action combines Paolos with Hatano, Watts and Tanida to suggest that the Applicants' invention as a whole would have been *prima facie* obvious. Applicants submit that the deficiencies in the individual references are not remedied by their combination. Moreover, when the combination of these references are considered for their entirety, they fail to teach or suggest the Applicants' invention as a whole. In particular, as mentioned above, Tanida and Hatano both require multiple coatings to a HPMC capsule to provide enteric or colonic drug delivery system. Applicants surprisingly achieve an enteric and colonic drug delivery system having a HPMC capsule that has a single aqueous coating. It is a well settled principle that to establish a *prima facie* case of obviousness of a claimed invention under 35 U.S.C. §103, all the claim limitations must be taught or suggested by the prior art. MPEP 2143.03, *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Accordingly, the cited references, when taken for the entirety of their teachings, cannot be considered to teach or suggest the Applicants invention. Thus, the rejections of the claims based on the combination of the cited references is inappropriate and withdrawal of the rejections and reconsideration is respectfully requested.

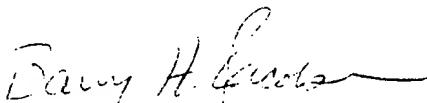
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In view of the present Amendment and Response, Applicants submit that the Application is in condition for allowance and favorable reconsideration is therefore respectfully requested.

Applicants have enclosed herewith 2 pages of formal drawings.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the number listed below.

Respectfully submitted,



Dated: January 14, 2002

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VERSION OF AMENDED CLAIMS WITH MARKINGS

TO SHOW CHANGES MADE

1. (Amended) A drug delivery composition comprising a HPMC capsule containing the drug and wherein the HPMC capsule is provided with a single aqueous coating such that the drug is not released from the capsule in the stomach.

10. (Amended) A drug delivery composition according to claim 2 wherein the coating comprises a copolymer of methacrylic acid and methylmethacrylate [(Eudragit L®)].

FIG-1 RELEASE PROFILE OF ACETAMINOPHEN FROM HPMC CAPSULES COATED WITH VARIOUS QUANTITIES OF EUDRAGIT L30D-50

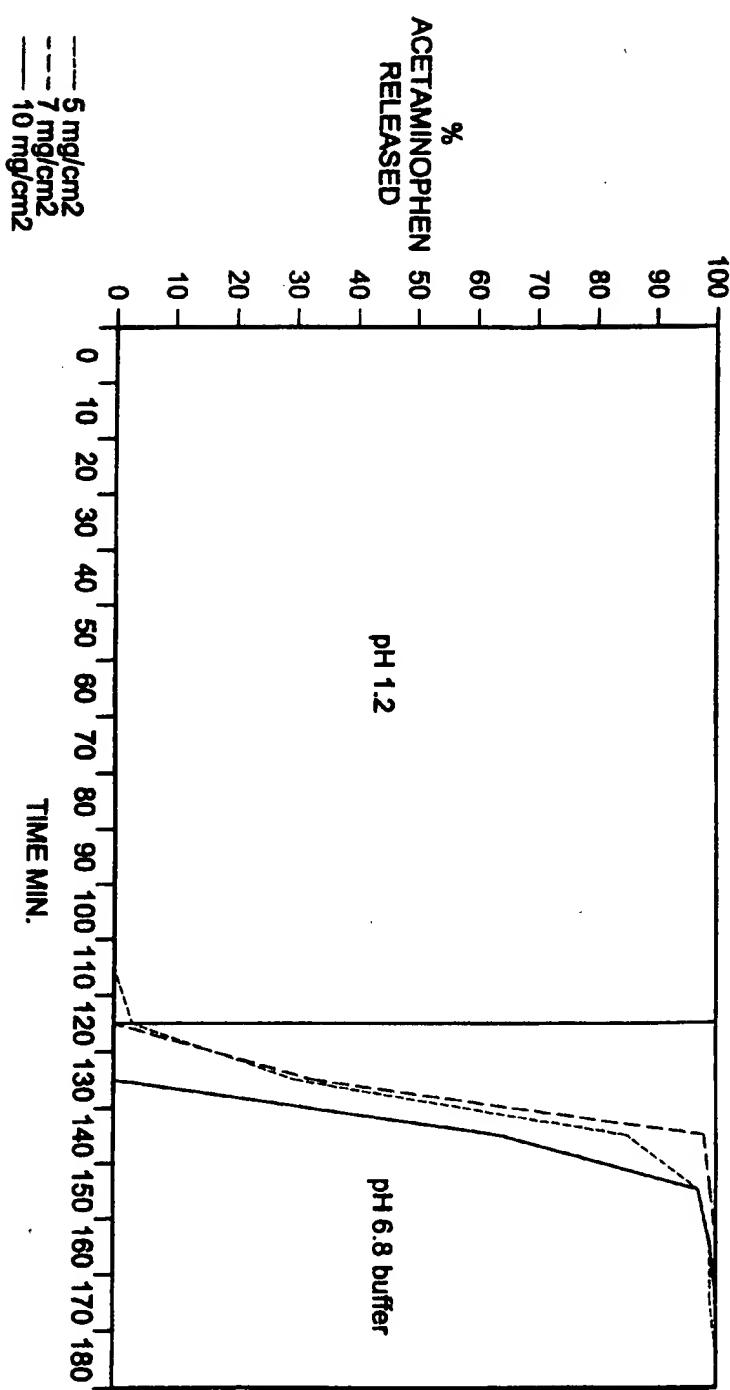


FIG-2

**RELEASE PROFILE OF ACETAMINOPHEN FROM HPMC CAPSULES COATED WITH
8 mg/cm² OF PREPARATION 4110D**

